Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	**Just In Time**:	**Small Bus. Set-Aside** [ ]Yes [X]No **8(a) Set-Aside**: [ ]Yes [X]No **NAICS Code:** 541710 **Size Standard:** 500 employees	**Level of Effort:** [ ] Yes [X] No **Total Effort:** [N/A]
NIH-NIAID-DAIT-03-22	[ ] Yes [X] No		

TITLE:

Primary Immunodeficiency Disease (PID) Consortium

Issue Date: 08/13/2002	**Due Date:** 01/06/2003 **Time:** 4:00 PM, EST	**Technical Proposal Page Limits:** [X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:

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[X] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:

[X] Only 1 Award
[X] with 1 Option
[ ] Multiple Awards

PERIOD OF PERFORMANCE:

5 years beginning on or about 09/02/2003

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT -- Erin Goldstein --COLLECT CALLS WILL NOT BE ACCEPTED--

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Updated thru FAC 97-25 (05/02/01)

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INTRODUCTION

This Request for Proposals (RFP) reflects the continuing commitment of the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute for Child Health and Development (NICHD) to advancing research in the field of primary immunodeficiency diseases. The RFP details two (2) different Parts, each with its own Statement of Work.

PART A solicits proposals to establish the Primary Immunodeficiency Diseases Consortium (hereinafter referred to as the Consortium), a cooperative group of investigators to promote and foster excellence in primary immunodeficiency disease research. The Consortium will be governed by a Steering Committee composed of primary immunodeficiency disease investigators to provide leadership and mentoring, facilitate collaborations, and enhance coordination of research efforts. The Consortium shall solicit, peer-review, recommend and award pilot or small clinical, pre-clinical and basic research projects to Consortium members and non-members, including new investigators. In addition, the Consortium will establish and maintain for the life of the contract a Primary Immunodeficiency Diseases Registry (hereinafter referred to as the Registry). The Consortium Contractor shall transition patient and physician data from the current NIAID Primary Immunodeficiency Diseases Registry (Contract N01-AI-75328 awarded to the Immune Deficiency Foundation) to the new Registry. The Consortium shall ensure maximal patient enrollment and follow-up, and investigator utilization of the Registry.

PART B (OPTION) solicits proposals to expand the Registry by creating and managing a repository of cell lines derived from registered individuals. The Option may be exercised at the discretion of the Government based on scientific needs, and opportunities and the availability of funds. The Contractor shall generate, expand, and store cell lines from Registry patient specimens and provide these cell lines to qualified investigators, in a non-viable form, as a source of DNA for approved research studies.

OFFERORS SUBMITTING A PROPOSAL UNDER THIS SOLICITATION MUST PREPARE A SEPARATE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL FOR EACH PART THAT INCLUDES THE REQUIRED WORK OUTLINED IN BOTH PART A and PART B. PROPOSALS FOR PART A ALONE OR PART B ALONE WILL NOT BE ACCEPTED FOR REVIEW OR CONSIDERED FOR AWARD.

It is anticipated that one (1) contract will be awarded for a period of five (5) years. Support for the activities in Part B of this solicitation may be initiated only when and if (1) additional funds become available; (2) the state of the science warrants implementation; and (3) the Government exercises the OPTION.

BACKGROUND – PART A

In its 1999 report, "International Benchmarking of U.S. Immunology Research," the Institute of Medicine concluded that the United States is the preeminent leader in most areas of immunology research, but has not achieved a level of preeminence in primary immunodeficiency disease research. To address this conclusion, the NIAID, in collaboration with the National Cancer Institute (NCI) and National Institute of Child Health and Human Development (NICHD), convened a primary immunodeficiency disease advisory panel, in September 2001, to identify impediments to investigators, gaps in knowledge that should be addressed, areas of research emphasis, and scientific opportunities. The Panel was also charged with making recommendations for approaches that the National Institutes of Health (NIH) might initiate to overcome obstacles, accelerate basic and clinical research in primary immunodeficiency diseases, and encourage the entry of new investigators into the field.

In particular, the advisory panel acknowledged that the rarity of these diseases places severe limitations on the numbers of patients available for research, precluding large clinical studies that are often favored in the traditional NIH investigator-initiated grant process. In addition, there are few funding opportunities for projects of limited scope, such as the molecular and cellular characterization of patients with rare phenotypes. The panel recognized The European Society of Immunodeficiencies, a network of European primary immunodeficiency disease investigators, as a successful model for addressing these problems by promoting primary immunodeficiency disease research through collaborative efforts. The advisory panel recommended a similar approach, incorporating three fundamental components from the European model: 1) formation of a cooperative network of primary immunodeficiency disease investigators; 2) establishment of a mechanism for awarding peer-reviewed small, short-term projects for innovative studies; and 3) creation of a short-term course for mentoring new investigators. The provision of funds for small research projects to promote primary immunodeficiency disease research and to assist and encourage new investigators was deemed an important component to accelerate and enhance research in this field. The types of small studies recommended for consideration included the clinical, cellular, and molecular characterization of unique phenotypes, and novel studies based on limited preliminary data or numbers of subjects. Studies of these rare diseases, including unique phenotypes, will also advance understanding of basic immune mechanisms and provide insight into unknown or unique pathways important in normal immune function. In addition, the panel felt that a unified network of experienced investigators would promote excellence and advancement in primary immunodeficiency disease research by providing leadership and mentoring for clinical and basic investigators new to the field, facilitating interactions and collaborations, and coordinating the sharing of resources and reagents.

The advisory panel also made recommendations concerning the existing NIAID-funded primary immunodeficiency disease Registry. In September 1992, NIAID awarded a contract (Primary Immunodeficiency Diseases Registry Contract N01-AI-75328) to the Immune Deficiency Foundation to establish a registry for U.S. residents affected by Chronic Granulomatous Disease (CGD). This contract was considered a pilot project to determine the feasibility and value of establishing a more comprehensive primary immunodeficiency disease registry. In a 1996 review, the Scientific Advisory Committee of the CGD Registry concluded that the registry had generated a considerable amount of new information on the disease and its prevalence. Later that year, a workshop convened by NIAID and NIH Office of Rare Diseases determined that a clinical registry for additional primary immunodeficiency diseases was essential to compile clinical information, develop accurate estimates of prevalence, and provide access to patients for pre-clinical and clinical studies and clinical trials. As a result, in 1998, the NIAID established a primary immunodeficiency disease Registry through the award of a five-year contract to the Immune Deficiency Foundation. Clinical data have been collected from approximately 1,500 patients with eight diseases: CGD, Hyper-IgM Syndrome, Severe Combined Immunodeficiency, X-linked Agammaglobulinemia, Wiskott-Aldrich Syndrome, Common Variable Immunodeficiency, Leukocyte Adhesion Deficiency, and DiGeorge Syndrome. Investigators have initiated sixteen projects to use the registry, resulting in three publications, and provided the most comprehensive clinical characterization of CGD to date. Two additional manuscripts are in preparation characterizing patients with X-linked Hyper-IgM Syndrome and X-linked Agammaglobulinemia. The September 2001 advisory panel concluded that: (1) registries for rare diseases are essential for compiling clinical information and developing accurate estimates of prevalence; (2) registries serve to unify communities of investigators through opportunities for collaborations and identification of potential research subjects for clinical and pre-clinical study referrals; and (3) placing the Registry under a network of primary immunodeficiency disease investigators, coupled with the ability to fund primary immunodeficiency disease-related small or pilot studies, will greatly enhance Registry utilization and value.

Statement of Work – Part A
Primary Immunodeficiency Disease Consortium
RFP DAIT-03-22

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below.

Specifically the Contractor shall:

1. **Establish the primary immunodeficiency disease Consortium, a cooperative network of investigators capable of providing the scientific, clinical, technical, and administrative expertise necessary to develop and implement a long-range plan to:**

    a. Rapidly address emerging opportunities and accelerate research in primary immunodeficiency diseases, through the establishment and implementation of procedures to solicit, review, prioritize, amend as necessary, recommend approval, and fund research proposals from Consortium members and non-members, for pilot or small clinical and pre-clinical research studies.
    b. Develop and implement collaborations, including the sharing of research resources.
    c. Provide mentoring to new investigators through educational activities and support for the conduct of pilot studies.
    d. Establish and maintain for the life of the contract a Primary Immunodeficiency Diseases Registry, including the transition of all patient data from the existing NIAID-funded Registry. Ensure maximal enrollment and investigator usage of the Registry. Review proposed studies, recommend for approval, and provide access to Registry data or patients for approved studies. **[See Note 1]**

2. **Establish an organizational and staffing structure for the scientific, technical, and administrative management, governance and coordination of the Consortium. [See Note 2]**

    Establish a Consortium Steering Committee (SC) that will serve as the main governing body and provide scientific leadership and direction for the overall governance of the Consortium. The Consortium PI will chair the SC and its membership shall include the NIAID Project Officer and a NICHD program officer, both in a non-voting capacity, and six primary immunodeficiency disease investigators, including leaders in primary immunodeficiency disease research. SC membership shall be limited to no more than one NIH intramural investigator, who may serve as a voting member. The Director for the Primary Immunodeficiency Registry shall be excluded from SC membership. Additional investigators may be added to the SC membership by majority vote of the SC as need requires, with the NIAID Project Officer's concurrence. The SC tasks shall include, but not be limited to:

    a. The Consortium PI will be responsible for the implementation of the overall direction, management, and coordination of all aspects of the Consortium's activities, and for the implementation of decisions made by majority vote of the Consortium SC.

    b. The PI must be a leading academic investigator in primary immunodeficiency disease research, a non-Federal employee, and must devote at least 10% effort to the contract.

    c. Develop and revise, as necessary, the Consortium's scientific agenda and establish priorities among various research needs and opportunities.

    d. Design and implement policies, procedures, formats, timelines and evaluation criteria for the solicitation and peer review of research proposals and proposed budgets.

    e. Develop and implement guidelines, policies, procedures and requirements regarding conflict of interest on the part of Consortium members, peer-review Advisory Panel members [see Statement of Work 3.a.2)b)], and Consortium-supported investigators, including the disclosure of financial interests relevant to research to be carried out under this contract. These policies, procedures and requirements shall be designed to enable the Consortium to meet the requirements for Federally-funded research. All Consortium members, peer review Advisory Panel members, and Consortium-supported investigators will be required to comply with all such policies and procedures.

f. Make final funding recommendations to the NIAID Project Officer and manage the implementation and evaluation of the progress and productivity of Consortium-supported research studies.

g. Provide overall direction and assessment of the scope, utility and productivity of the Registry.

h. Establish subcommittees, e.g., policy, scientific review, and human subjects protection, as needed for addressing various issues related to the scientific, technical and administrative management of the Consortium.

i. Submit a final proposal of the complete scientific agenda, including guidelines, policies, procedures and requirements to the NIAID for approval within 60 days after the award of the contract. In addition, guidelines, policies, procedures and requirements regarding conflict of interest on the part of Consortium members, peer-review Advisory Panel members, and Consortium-supported investigators shall be included.

j. Convene no fewer than two (2) one-day meetings per year, to be held in the Bethesda, Maryland area. The first meeting of the SC shall be held within 45 days of the contract award. The SC shall also conduct conference calls at least once every two months. **[See Notes 3 and 4]**

3. **Develop and implement a detailed scientific agenda to foster and expand clinical, pre-clinical and basic research on primary immunodeficiency diseases.**

Specifically, design and implement plans, policies and procedures to:

a. **Solicit, review, prioritize, amend as necessary, recommend approval, and fund research proposals from Consortium members and non-members, for pilot or small clinical and pre-clinical research studies.** The major focus of projects to be funded shall be human research studies, including the clinical, molecular and cellular characterization of patients with novel primary immunodeficiency disease phenotypes. Clinical trials, including experimental therapeutic and preventive strategies, epidemiological and prevalence studies, as well as behavioral and educational intervention research will not be supported under this contract. However, under exceptional circumstances and subject to NIAID Project Officer review and approval, review and funding of a high impact, low cost clinical trial may be authorized. Support shall be provided for mechanistic, biomarker or other research studies utilizing patient samples or data associated with ongoing or completed clinical trials supported by other Federal and/or private sources. At least 75% of the funds dedicated to research projects under this contract shall be used for human subjects research and no more than 25% shall be used to support animal studies. **[See Note 5]**

1) **Solicit proposals for research projects** from a broad spectrum of clinical investigators and basic scientists, including Consortium members and non-members. A detailed protocol for the solicitation and review process shall be submitted for approval to the NIAID Project Officer within 60 days of the award of the contract (see paragraph 2.c., above). Solicitation of proposals shall begin within three months of the contract award date.

a) Develop and refine, as necessary, the scope, priorities and types of research projects eligible for consideration, and the criteria to be used to evaluate scientific merit and feasibility
b) Develop policies, procedures, time frames, formats, and requirements for the preparation and submission of proposals, including the provision of advice and technical assistance to interested investigators in developing proposals;
c) Develop and implement multiple and varied methods for disseminating information on the procedures and policies regarding research project submission and review.
d) Develop and incorporate specific methods for reaching and encouraging proposals from new investigators. **[See Note 6]**

2) **Evaluate the scientific merit and feasibility of the research project proposals.**

Specifically,

a) Design, develop and implement a detailed peer review plan, incorporating the following minimum components:

(1) criteria to be used to assess scientific merit and feasibility with particular attention to criteria applicable to the evaluation of pilot or small studies and to the evaluation of proposals from new investigators;
(2) procedures for scoring, ranking and recommending approval/disapproval;
(3) procedures and formats for recording the outcomes of the peer review process and for the provision of such documentation to the NIAID Project Officer and the investigator;
(4) timing and frequency of review cycles; and
(5) policies regarding acceptance of revised proposals and the number of revisions to be permitted.

b) Establish a peer review Advisory Panel (AP) with responsibility for evaluating, ranking, documenting peer review outcomes, and making funding recommendations to the Consortium SC. No more than 40 percent of the AP membership for any review shall be members of the Consortium SC. Non-SC members of the AP will be volunteer members. Advisory Panel peer review meetings shall take place at least three times annually, except at least twice annually during the first year and final year of the contract. Advisory Panel meetings may be conducted via teleconference. Develop, implement and administer policies, guidelines and procedures to avoid real or potential conflicts of interest in the peer review and recommendation process on the part of AP members. This shall include policies governing the disclosure of financial and other interests, the review of such disclosed information, and methods for resolving real or potential conflicts. (See Statement of Work, paragraphs 2.e. and 2.i.) The research studies funded by the Consortium may be awarded to investigators from foreign institutions if they advance United States scientific standing in primary immunodeficiency research. **[See Note 7]**

3) **Review AP recommendations, prepare and submit recommendations to the NIAID Project Officer, and fund approved research projects.** The Consortium SC shall review the recommendations of the AP and submit final recommendations to the NIAID within three weeks of the AP review with respect to: (a) approved proposals recommended for funding, including recommended annual and total project costs; (b) proposals recommended for revision and resubmission; and (c) proposals disapproved. Support for the research studies will be limited to between $50,000 and $150,000 per year in direct costs for 1-2 years. Under exceptional circumstances, the Project Officer may elect to review and give written approval for Consortium peer-review and subsequent consideration of funding for research proposals requesting direct costs greater than $150,000 and/or more than 2 years. **[See Note 8]**

4) **Evaluate progress and productivity of Consortium-funded investigators and research projects.** This shall include:

a) Establishment of criteria for measuring progress and productivity.
b) Development of reporting requirements and appropriate formats.
c) Procedures for the review of written information on study status, progress and problems, including guidelines and procedures for investigators to obtain assistance, advice and mentoring in relation to funded research projects.
d) Design and implementation of mechanisms to modify or curtail projects based on less than satisfactory progress.
e) Methods to promote the publication of study results. **[See Notes 9 and 10]**

b. **On an ongoing basis, identify opportunities for coordinating research studies and fostering appropriate collaborations** to enhance the investigations supported by the Consortium, including the sharing of important research resources and use of data from the primary immunodeficiency disease Registry. This includes: (i) developing and facilitating collaborative activities; (ii) coordinating research projects with similar objectives, including arranging for joint investigations among Consortium-supported researchers; and (iii) identifying the need for shared research resources and implementing appropriate arrangements for the provision of such resources to Consortium-supported investigators.

c. **Design and implement a plan for mentoring investigators new to the field of primary immunodeficiency disease research,** including, but not limited to:

1) conducting at least one short-term course or conference per year, beginning the second year of the contract, targeted at new investigators and conducted by senior investigators in a mentoring capacity, and

2) funding small pilot projects for new investigators that incorporate mentoring, if necessary, and critiques from experienced investigators. **[See Notes 6 and 11]**

4. **Develop and implement a scientific agenda to establish and manage a Primary Immunodeficiency Disease Registry** (hereinafter referred to as the Registry) This shall include ensuring, at a minimum: (i) the timely transition and incorporation of patient and physician data from the existing NIAID-funded Primary Immunodeficiency Disease Registry into the new Registry; (ii) maximal enrollment and follow-up of registered patients; (iii) maximum utilization of the Registry by investigators for both basic research studies and clinical trials; and (iv) reporting and publication of research studies utilizing Registry resources.

   Specifically, the contractor shall:

   a. **Establish and maintain for the life of the contract a primary immunodeficiency disease registry.** Initiate development of the Registry within two (2) months of the contract award and complete establishment of the Registry within six (6) months. Develop, provide in detail, and implement transition plans for incorporation of patient and physician data from the existing Registry. Develop and implement plans for the collection, organization, quality control, and dissemination of clinical information. Such Registry information shall include, but not be limited to: clinical phenotype, medical history, personal information, current health status, medications, effects of therapy, prognosis, cause of death, and results of laboratory tests and genetic analyses on all persons residing in the U.S. affected by the following primary immunodeficiency diseases: Severe Combined Immunodeficiency Disease (SCID), X-linked Agammaglobulinemia (XLA), Wiskott-Aldrich Syndrome (WAS), Common Variable Immunodeficiency (CVID), Chronic Granulomatous Disease (CGD), DiGeorge Syndrome, Leukocyte Adhesion Deficiency (LAD), and Hyper-IgM Syndrome. The percent effort for the Director of the Registry shall be limited to between 15% and 20%. **[See Note 12]**

   b. **Establish and maintain a comprehensive data management system of the Registry:**

      1) develop a database using commercially available hardware and software that provides sophisticated searching capabilities and controlled access to protect the privacy of the physician/patient information;
      2) implement a plan to address database security issues;
      3) maintain a backup copy of the computerized database to protect against accidental loss of valuable data; and
      4) develop and provide web-based, limited-access to specified, approved data by approved users.

   c. **Develop and implement a plan to ensure maximal registry enrollment,** including methods and procedures for the acquisition of relevant clinical information that ensure all required information is accurately obtained. Include provisions for Registry staff to assist physicians with multiple patient registration and provisions for electronic and web-based patient registration capability. **[See Note 13]**

   d. **Develop and implement a plan to collect follow-up clinical data once every two years on all registered individuals**, beginning the first year of this contract for all previously registered individuals who have not had follow-up in the past two years. Clinical data shall include, but not be limited to: current medical status and an update on laboratory results; infections incurred; medications and therapeutics received; and adverse events.

   e. **Establish a voluntary Scientific Advisory Committee (SAC) or committees,** composed of 5 or more scientists who conduct research in primary immunodeficiency diseases, to establish and/or approve definitions for each disease, the data entry forms, and access to the Registry for appropriate scientific purposes. The Consortium SC shall appoint the SAC. Consortium SC and AP members may serve in this capacity. **[See Note 14]**

   f. **Develop and implement a plan to enhance utilization of the Registry by investigators,** including methods for advertising to the scientific community the opportunity for Registry-related research, as well as access to other Consortium resources including funds to facilitate Registry-related studies.

   g. **Disseminate Registry information to SAC/SC approved users** and establish requirements for progress report filing by approved users on research conducted with Registry data or patients. Consortium membership, award of a Consortium-supported research project, or SAC/SC approval to use the Registry requires the investigators' agreement to participate in the Registry through enrollment of their primary immunodeficiency disease patients. **[See Notes 15]**

5. **Develop and implement Consortium and Registry close-out and transition plans which detail**:

   a. A protocol for the delivery of the Registry contents, including full documentation of the organization of the information and access, to the NIAID Project Officer or the designee at an appropriate transition point, at least 90 days prior to the expiration of the contract.

   b. A plan detailing how clinical materials and data from pilot studies can be accessed and to whom future access will be allowed.

[End of Statement of Work for Part A]

BACKGROUND – PART B OPTION

Expansion of the Primary Immunodeficiency Disease Registry to include a cell repository as a source of DNA.

BACKGROUND – PART B - OPTION

A key component of NIAID's mission is to promote and facilitate research into the causes and mechanisms of immune-mediated diseases. Because of the rarity of primary immunodeficiency diseases, a readily accessible, centralized repository of immortalized cells, as a DNA source, well-characterized patients would provide a critical and valuable resource to researchers. Such a resource would facilitate genetic analyses that offer opportunities to understand how diverse genetic defects can result in the same or similar disease phenotypes and how similar or identical genetic defects result in different disease phenotypes, based on the genetic differences between patients. Defining the conditions that result in similar or dissimilar disease phenotypes offers tremendous potential for advancing our understanding of basic immune mechanisms and the pathogenesis of primary immunodeficiency diseases. The availability of a repository will serve as a stimulus for the generation of novel hypotheses and allow the primary immunodeficiency disease research community to capitalize on related immunogenetic discoveries.

Statement of Work – Part B (OPTION)
Primary Immunodeficiency Disease Consortium
Option to Expand the Primary Immunodeficiency Disease Registry to include a cell repository as a source of DNA
RFP DAIT-03-22

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contracts, as needed to perform the work set forth below.

Specifically, the Contractor shall:

1. **Establish and maintain for the life of the contract a cell repository** (hereinafter referred to as Repository) from Primary Immunodeficiency Disease Registry patients for distribution in the form of non-viable cells as a DNA source. This shall include establishing: policies and protocols for the collection and shipment of cells or tissue by investigators/physicians (Submitters) to the Repository; policies for informed consent related to IRB submissions and approvals and ethical considerations; procedures for the generation, quality control, storage and shipment of cell lines; criteria for approval of genetic study requests, including proper institute assurances, and procedures for release approvals by the registering physician/investigator; and procedures for data and inventory monitoring, security and management. **[See Note 16]**

2. **Develop and implement plans and protocols to:**

   a. **Provide physicians/investigators with procedures for the proper collection**, labeling, and shipping of specimens, and procedures to ensure proper patient informed consent and meet IRB requirements. Obtain specimens, peripheral blood or skin biopsy, from previously and newly registered individuals.

   b. **Establish and expand immortalized cell lines from specimens**, using procedures that ensure freedom from contamination by infectious agents and other cells, and establish quality control procedures to ensure that specimens are negative for HIV and other human pathogenic agents and that cell lines are free from contamination by bacteria, fungi and mycoplasma. The Contractor shall perform additional quality control on a minimum of 10% of the cell lines established, including, but not limited to, tests specific to identify the cell type, freeze/thaw viability and tests, such as DNA fingerprinting, to demonstrate identity to the original cell specimen.

   c. **Freeze and store the following of each cell line**. Five vials of at least 5 million cells each will be frozen and stored under conditions in which maximal viability is retained. Two of these five vials will be stored at an off-site facility as a safeguard against accidental loss of this valuable collection. These 5 vials are for future expansion of the cell line. An additional 5 vials, containing at least 2.5 million cells each, as a dry pellet, shall be frozen to supply directly as non-viable cells for approved studies. The cell line shall be re-expanded when only 1 vial of dry pellet cells remains. Investigators requesting and receiving the cells will perform their own DNA extraction from the non-viable cell pellet.

   d. **Conduct research for optimization of collection, immortalization, expansion, and freezing techniques.**

   e. **Maintain appropriate storage conditions and facilities** and appropriate procedures for the provision and shipment of non-viable cells for approved studies.

   f. **Review research proposal requests to obtain Repository non-viable cells for DNA isolation**. The advisory/review panel established for the Registry, or other committee decided upon by the Consortium SC, will review and approve proposals for the use of these Repository resources. Final approval of distribution shall rest with the Project Officer, who may delegate this responsibility to the Consortium PI under guidelines formulated by mutual agreement. **All cell lines developed under this contract shall be the property of the Government. No DNA obtained from the Repository may be used for therapeutic applications. [See Note 17]**

3. **Provide and maintain a computerized specimen inventory management system.**

   a. Maintain a comprehensive computerized database that shall include, but not be limited to, records on individual cell lines linked to Registry data and the status of the cell line, inventory of remaining frozen stock, number of cell generations or passages at the time of freezing, quality control information, requests, shipments, and bibliographic references about specific cell lines.

   b. Provide, along with SC approved shipments of non-viable cell lines, all related Registry information and bibliographic references.

   c. Maintain a backup copy of the computerized database to protect against accidental loss of valuable data.

4. **Provide the appropriate facilities and resources to perform all components of the Statement of Work, Part B,** including, but not limited to, laboratories, equipment and supplies for the establishment, quality control, and storage of cell lines; and computers and appropriate software for the inventory management system.

5. **Establish a protocol for transition plans** which details the delivery of the Repository documentation, contents, government-owned equipment and property, including full documentation of the information organization, storage protocols and access to the NIAID Project Officer or designee at an appropriate transition point 90 days prior to the expiration of the contract

END OF STATEMENT OF WORK – PART B (OPTION)

Notes To Offerors – PART A

Primary Immunodeficiency Disease Consortium
RFP DAIT-03-22

Note 1
Offerors shall have flexibility in proposing a Consortium structure capable of meeting the requirements of this work statement, including establishing criteria for Consortium membership. The Consortium will require strong leadership to: provide overall scientific direction; manage the Registry and ensure maximal enrollment; develop and implement processes and criteria for research study proposal peer-review, award and oversight; design and carry out mentoring programs; and develop and implement plans for resource sharing. Formation of a collaborative group of investigators with a broad range of scientific and clinical expertise in primary immunodeficiency disease will be necessary to carry out the requirements of this work statement. The Government recognizes that no single institution or organization will have the expertise and facilities necessary to perform all requirements and, therefore, it will be necessary for the Prime Contractor to subcontract portions of the work to be performed.

Not more than 25% of the total funds awarded under this contract shall be used for the scientific, technical, policy and administrative infrastructure required to lead and manage Consortium and Registry activities. Not less than 75% of the total funds awarded for the contract shall be used to support the clinical, pre-clinical, and basic research studies, and the mentoring program.

Note 2
Proposals must include a plan, which addresses each specific requirement/item set forth in the Statement of Work. The Technical Proposal shall include a detailed plan describing the organizational components of the Consortium and lines of authority, as well as the roles and responsibilities of all scientific, technical, and administrative staff. The Offeror shall provide a chart illustrating organizational structure and chain of command, operating procedures, timelines, and decision-making processes. In addition, the Offeror shall provide documentation of the qualifications of the technical and administrative staff proposed to carry out the requirements of this contract, including all previous and current projects of a similar nature, including the grant or contract number, the sponsoring agency, the Project Officer, and description of the project. The Offeror shall include in the Technical Proposal documentation of the qualifications, knowledge, experience, education, competence, success in designing, implementing, completing and publishing the results of research studies, and availability and decision-making skills of the proposed Principal Investigator (PI) and proposed Steering Committee (SC) members (see work statement item II A. and note 3). Briefly discuss how the Consortium will continue operations were the PI to become unable to conduct his/her responsibilities as PI.

Note 3
The Offeror shall include in the Technical Proposal a description of the functions of all proposed committees, subcommittees or panels, including the SC. The Offeror shall include the names the six proposed SC members, and should include the names of any other Consortium members who have been identified. An NIH intramural investigator may serve as a voting member of the SC, but they may not receive salary, travel reimbursement, equipment, supplies, or other remuneration from this Contract or Consortium.

Note 4
Curricula Vitae, limited to four (4) pages each, of all proposed personnel shall be included in an appendix to the Technical Proposal. All costs associated with proposed personnel, including travel costs to attend SC meetings for all non-NIH Committee members and essential support staff, shall be provided in the Business Proposal.

Note 5
Human subjects research studies may also include research to develop new diagnostics and innovative therapeutic strategies, research to identify new biomarkers, and research to elucidate the underlying mechanisms of disease. In addition, the scientific agenda may address basic research needs and opportunities, including research in animal models and the development of new animal models.

Note 6
A primary objective of funding new investigators is to enable them to acquire preliminary data that will lead to a successful NIH R01 grant application. The Offeror shall discuss what efforts will be made to encourage applications from new investigators. A new investigator is defined as a scientist who has never served as the Principal Investigator of an NIH R01 or Veterans' Administration Merit award, or an investigator who is new to the field of primary immunodeficiency disease research.

Note 7
Applications that have the potential to become future NIH R01-supported research projects shall be given a priority.

Note 8
For purposes of preparing the Business Proposal assume that there will be a total of $1,600,000 available for the funding of the small research projects per year (total costs), including the second year costs for projects approved for two years.

Note 9
The Offeror shall submit a minimum of two (2) and no more than four (4) detailed collaborative proposals for pilot or small studies related to primary immunodeficiency disease that are representative of projects anticipated for funding. The proposed studies shall serve as examples to the primary immunodeficiency disease community. The Government anticipates that it is possible that Consortium members and collaborators may carry out one or more of the proposed studies over the course of the contract. However, the award of this contract does not commit the Government to approve funding of the proposed studies. An estimate of direct costs for each proposed study must be included in the Technical Proposal for review purposes. However, if the Government approves the proposed studies to go forward, the awards will come from the funds delineated in the Business Proposal for pilot or small research grants. Therefore, the Business Proposal shall include total expected funding for such projects (see Note 8). Registry use is not required for these proposals. However, at least two (2) of the proposed studies must be human subjects research. If a proposed study will involve the use of biological specimens or data from a clinical trial or other study supported by non-consortium funds, letters from the PI of the clinical trial or study and the funding entity of the clinical trial agreeing to participation must be provided in the Technical Proposal.

Note 10
The Offeror shall submit a detailed proposed scientific agenda addressing all components of Statement of Work, paragraph 3. The Technical Proposal shall also include:

(a) A brief description of knowledge gaps and scientific opportunities relevant to primary immunodeficiency research and obstacles to progress in this field.

(b) A conceptual framework briefly describing: (i) how scientific research priorities will be established; (ii) plans for communicating to the scientific community at large regarding Consortium priorities and resources; (iii) the types and scope of studies anticipated to be funded; (iv) proposed format and requirements for small project proposals; (v) methods to include and encourage proposals from new investigators; (vi) potential resource needs that would best be shared among multiple investigators and strategies for how such resources might be provided, as well as methods and plans to facilitate coordination of efforts and foster collaborations; and (vii) mentoring plans,including a description of plans for a short-term course for new investigators. (See Note 11.)

(c) A detailed plan for review of research proposal applications, including timing related to submission, number of revisions, development process, review cycles, description and make-up of the review group, review, scoring, selection and award procedure. In addition, the plan shall describe how the SC will evaluate the pilot and small studies. The Offeror shall give guidelines for potential conflicts of interest and detailed plans about how conflict of interests will be avoided in the review, approval and awarding of small or pilot projects. In addition, other advisory roles may be proposed for the AP, including Primary Immunodeficiency Disease Registry advisory roles, or other volunteer panels or subcommittees of the SC that may be established.

It is anticipated that 6-10 pages each will be adequate to address the two (2) to four (4) study proposals for pilot or small studies.

Note 11
For budgeting purposes only, the Offeror should assume a single four nights/five days short course per year will be conducted in the continental United States and that the course will comprise 10 faculty members and approximately 30 student participants. For the preparation of the Business Proposal include travel, food and lodging for faculty members, but only food for student participants. Assume no registration fee will be charged.

Note 12
The Offeror shall address in detail of all components of Statement of Work, paragraph 4., and if proposing a Subcontractor, the work statement and selection of the Subcontractor, a management plan detailing how the Contractor will coordinate the work of the Subcontractor, a complete description of the Subcontractor's facilities and professional background and capabilities of the proposed Director of the Registry and of all other personnel. The Offeror must provide a detailed plan and timeline in the Technical Proposal for the timely transition and incorporation of data from the existing NIAID-funded Registry to the new Registry. Clinical data entry forms used by the existing Registry for the eight primary immunodeficiency diseases are provided as an attachment to the SOW. The Registry currently uses a Microsoft Access 2000 software database. The existing Registry has approximately 1500 individuals registered.

Note 13
The Government anticipates the Registry will be physician-based, as is the existing Registry. Briefly address the advantages and disadvantages of this physician-based registry approach. In particular, address aspects of registry approaches that involve ensuring maximal registry enrollment. The Offeror may propose and justify inclusion of other registry approaches.

Note 14
The Offeror should address how conflicts of interest will be identified, disclosed, reviewed, and managed. (See Statement of Work, paragraphs 2.e. and 3.a.1)b). Address the frequency of SAC meetings and how a speedy review and approval process will be ensured. The Government anticipates that SAC meetings will be conducted by teleconference.

Note 15
The Offeror shall separate the Registry costs from other Consortium activities and costs in the Business Proposal for Statement of Work Part A.

NOTES TO OFFEROR:
PART B - OPTION

Note 16
The Government recognizes that a single institution may not have the expertise and facilities required to perform all requirements of the Work Statement. Therefore, subcontracting agreements for a portion or all of the work in Part B are acceptable to and encouraged by the Government. In responding to Part B of this RFP, the Offeror shall describe in detail a management plan defining how the Contractor will coordinate the work of the Subcontractor, the selection of a Subcontractor, the responsibilities and level of effort of all proposed personnel who will be assigned to Part B, the administrative framework with clear lines of authority. Documentation should be provided on the qualifications, experience, education, competence, availability, and decision-making authority of the Director for the Repository and all key personnel, including responsibilities and level of effort for proposed personnel assigned to Part B; and the extent to which outside consultants will be used. Curricula Vitae should be no more than 4 pages per individual and should clearly demonstrate relevant training and experience. All costs associated with proposed personnel shall be provided in the Business Proposal. The Offeror shall provide a detailed work plan showing proposed time schedules for achieving contract objectives. In addition, the Offeror shall provide details about maintaining quality control over the implementation and operation of the contract.

Note 17
The Technical Proposal shall include a detailed proposal addressing all items in the work statements and relative experience in various procedures. In addition, the Offeror shall include the following:

(a) The Offeror shall discuss disease priorities in the context of a DNA repository and the research value of a DNA repository for each of the eight primary immunodeficiency diseases represented in the Registry. Discuss the specimen source required in each disease and discuss human subjects protection and ethical considerations regarding specimen collection. Provide a plan for how previously registered individuals, and in which disease priority order, if any, will be recruited to obtain cell or tissue specimens.

(b) It is anticipated that peripheral blood mononuclear cell transformations and in vitro expansion will be required to generate sufficient cell numbers to bank for distribution and to create a bank of cells for future expansions. In some cases, particularly in patients with combined B and T cell deficiencies, skin biopsies may be required for the propagation of fibroblasts. In addition, techniques to transform T cells may be required. Provide details and relevant expertise in these procedures. In addition, provide rationale for which technique or techniques will be used for which primary immunodeficiency disease. Relevant exp ertise shall be provided.

(c) Provide an estimate of the number of samples anticipated in the first and subsequent years of the contract. In order to prepare a Business Proposal, assume approximately 100 specimens will be submitted and 75-100 cell lines generated in the first year of the contract. In addition, assume approximately 150-200 samples a year will be added to the Repository in subsequent years. Assume the approved users will pay shipping costs. The Submitters of the patient specimens must provide assurances that the identity of donor subjects, or information through which the identity of the donor subjects may readily be obtained, will not be provided to investigators of approved studies. Data base security issues and unlinking of identifiers shall be addressed.

(d) Offerors may make alternate proposals, e.g. the inclusion of an option to provide viable cells to approved users or purify and supply DNA. Provide details for alternate proposals in the same depth required for this work statement.

REPORTING REQUIREMENTS AND DELIVERABLES

Primary Immunodeficiency Disease Consortium
RFP DAIT-03-22

TECHNICAL REPORTS

The Contractor shall submit electronically to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during the reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

1. **Semi-annual Technical Progress Reports -** The contractor shall submit the technical reports electronically, in addition to three (3) copies comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer on the 30th of the month following the end of each six-month period. Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due. Such reports shall include the following specific information:

   a. A cover page that lists the contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission;

   b. Section I – An introduction covering the purpose and scope of the contract effort;

   c. Section II – A description of the overall progress plus a separate description for each task or other logical segment of work on which effort was expended during the report period. Include and describe status and progress from mentoring programs and research projects reviewed and funded. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the Registry, Repository or any Consortium-funded studies. Progress and final reports submitted by investigators on all Consortium-funded projects as well as approved Registry or Repository studies shall be submitted along with the report;

   d. Section III – substantive performance; a description of current technical or substantive performance and any problems encountered which may exist along with proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have occurred and if behind planned progress what corrective steps are planned;

   e. An anticipated work plan for the next six months;

   f. Preprints and reprints shall be submitted along with the report.

2. **Annual Reports** - The contractor shall submit the Annual Progress Report on the 30th of the month following each anniversary date of the contract. This report shall be submitted electronically, in addition to three (3) hard copies comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall detail, document, and summarize the results of the entire contract work for the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. Also to be included in the report is a summary of work proposed for the next reporting period. In addition, the report should include a discussion of changes in operations or staffing, and other issues that have an impact on the performance of the contract, as well as other data as determined by the Project Officer. An annual report will not be required for the period when the final report is due. Preprints and reprints not submitted in the report shall be submitted.

3. **Final Report –**Thirty days before the completion date of the contract, the Contractor shall submit electronically the Final Report as above, in addition to three (3) hard copies of the Final Report, comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer. These final reports shall detail, document and summarize the results of the entire contract period of performance. These reports shall be in sufficient detail to explain comprehensively the results achieved. Preprints and reprints not included previously shall be submitted.

4. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

If the Contractor becomes unable to deliver the specified reports within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of any anticipated delays with reasons.

OTHER DELIVERABLES - *PART A*

1. Submit a final proposal of the complete scientific agenda, including guidelines, policies, procedures and requirements to the NIAID for approval within 60 days after the award of the contract. In addition, guidelines, policies, procedures and requirements regarding conflict of interest on the part of Consortium members, peer-review Advisory Panel members, and Consortium-supported investigators shall be included.

2. The Contractor shall submit to the NIAID the Steering Committee's recommendations with respect to the Advisory Panel's ranking of small research proposals reviewed that shall include: (a) approved proposals recommended for funding, including recommended annual and total project costs; (b) proposals recommended for revision and resubmission; and (c) proposals disapproved. The Contactor shall submit this information within three weeks of the AP review.

OTHER DELIVERABLES - *PART B* - *Option*

1. The Contractor shall prepare a User Manual of Standard Operating Procedures subject to Project Officer approval for all aspects of specimen collection, handling, processing, storage and shipment within 45 days of award.

2. Technical report requirements are as stated above with the addition that each report shall also include, at a minimum, a breakdown of the number of cell lines established and aliquots prepared and shipped. The report should also include data on the number of samples that failed to be established as cell lines and the reasons for the failures. Details of efforts to obtain specimens should be included, as well as other data as determined by the Project Officer.

SUBMISSION OF TECHNICAL REPORTS

Copies of the technical reports shall be submitted as follows:

Type of Report	No. of Copies	Due Date
Semi-annual Technical Report	1 – Electronic Copy 2 – Project Officer (paper) 1 – Contracting Officer (paper)	Due the 30th of the month following each 6-month period. Not due when Annual and Final Reports are due.
Annual Technical Report	1 – Electronic Copy 2 – Project Officer (paper) 1 – Contracting Officer (paper)	Due the 30th of the month following each anniversary date of the contract. Not due when Final Report is due.
Final Report	1 – Electronic Copy 2 – Project Officer (paper) 1 – Contracting Officer (paper)	Due 30 days prior to the completion date of the contract.
Summary of Salient Results	1 – Electronic Copy 2 – Project Officer (paper) 1 – Contracting Officer (paper)	Due with the Final Report.

Addressees:

Project Officer
Division of Allergy, Immunology and Transplantation (DAIT)
6700B Rockledge Drive; Room ___
Bethesda, MD 20892-7640

Contracting Officer
Contract Management Branch, DEA, NIAID, NIH
6700B Rockledge Drive, Room 2230, MSC 7612
Bethesda, MD 20892-7612

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment (Paragraph (a) is modified to delete the words Subpart 31.2 and to add the words Subpart 31.7)

52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs

52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-5	Sep 1996	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS – Rev. 05/2002]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

Alternate II (OCTOBER 2001) of FAR Clause 52.219-9, Small Business Subcontracting Plan (OCTOBER 2001) is added.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor. **[Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR 52.217-9, Option to Extend the Term of the Contract (MARCH 2000).

"(a) The Government may extend the term of this contract by written notice to the Contractor within [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION] ; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least days [60 days unless a different number of days is inserted] before the contract expires. The preliminary notice does not commit the Government to an extension."

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed [MONTHS/YEARS]."

FAR Clause 52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (OCTOBER 1999), is applicable to this solicitation.

FAR 52.224-1, Privacy Act Notification (APRIL 1984).

FAR 52.224-2, Privacy Act (APRIL 1984).

FAR Clause 52.237-3, Continuity of Services (JANUARY 1991), is applicable to this solicitation.

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

HHSAR 352.223-70, Safety and Health (JANUARY 2001) [This clause is provided in full text in SECTION J - ATTACHMENTS.]

HHSAR 352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (APRIL 1984).

HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

(a) **Definitions**. As used in this clause--

Commercial item, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: December 6, 2002 (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration (When applicable all institutions must have form reviewed and approved by their Institutional Review Committee.)**
- **Government Notice for Handling Proposals**
- **Targeted/Planned Enrollment Table**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format (if applicable)**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contacts**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **Inclusion Enrollment Report**
- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Privacy Act System of Records (System Notice 09-25-0200)**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION*: The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.

ELECTRONIC SUBMISSION*: *In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP-NIH-NIAID-DAIT-03-22
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Erin Goldstein Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Erin Goldstein Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES (PART A) and 50 PAGES (PART B) [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc. It is anticipated that 6-10 pages each will be adequate to address the two (2) to four (4) study proposals for pilot or small studies.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided by the Contract Specialist.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIT-03-22
RFP Title: Primary Immunodeficiency Disease Consortium

Please review the attached Request for Proposal. Furnish the information requested below and return this page by December 6, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Erin Goldstein
RFP-NIH-NIAID-DAIT-03-22
FAX# (301) 480-5253
Email : eg108r@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions.* As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that ONE will be made from this solicitation and that the award(s) will be made on/about September 2, 2003 .

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF Five (5) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately as follows:

PART A (Base Period of Contract):	5,358 labor hours per year (~2.6 FTEs/year)
PART B (Option):	2,820 labor hours per year (~1.4 FTEs/year)

This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

m. USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and

associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall perfo rmance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

1.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(9) through (14)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*****. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*****, (telephone: 301-496-7014*****), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR***** an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR***** and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR***** be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

*******Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/ Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.*

Instructions to Offerors Regarding Protection of Human Subjects

*****(Note: The requirements in this paragraph (10), may be supplemented when necessary, based on the specific requirements of the solicitation.) *****

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

– Describe the proposed involvement of human subjects in response to the solicitation.

– Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

– Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

– Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(10) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(11) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/OMB/fedreg/ombdir15.html*

.

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that*:* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference),

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

[1] See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

(12) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. **(See examples of Justifications for Exclusion of Children below).** For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The “Human Subjects” section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.

  – There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

  – The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.

  – A separate, age-specific study in children is warranted and preferable. Examples include:

- The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
- The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(13) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(14) **Care of Live Vertebrate Animals**

a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

(15) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(16) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.

- to the Department of Justice as required for litigation.

- to respond to congressional inquiries.

- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(17) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily and FedBizOpps.

(18) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference. (See SECTION J, Attachments, to this RFP for an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(19) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(20) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(21) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(22) **Salary Rate Limitation in Fiscal Year 2002** **

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

Information regarding the FY-2002 rate can be found at: http://www.opm.gov/oca/02tables/ex.pdf

It should be noted that a similar public law can be enacted in Fiscal Year 2003, that public law will be incorporated into any resultant contract.

(23) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(24) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(25) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

UNIFORM ASSUMPTION: FOR PURPOSES OF PREPARING THE BUSINESS PROPOSAL ASSUME THAT THERE WILL BE A TOTAL OF $1,600,000 AVAILABLE FOR THE FUNDING OF THE SMALL RESEARCH PROJECTS PER YEAR (TOTAL COSTS), INCLUDING THE SECOND YEAR COSTS FOR PROJECTS APPROVED FOR TWO YEARS.

(2) **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) **Information Other than Cost or Pricing Data**

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

   Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

(4) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

(5) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(6) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(7) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(8) **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(9) **Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(10) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and Small Disadvantaged (SDB). Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NCI that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

(c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/ gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health,;or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the prima ry analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

(d) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.
Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable."

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. **EVALUATION OF OPTIONS**

It is anticipated that any contract awarded from this solicitation will contain an option provision and period.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Complexity and variety of the work SDB concerns are to perform
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

5. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. **Part A (Registry and Consortium) and Part B (Repository) will be evaluated separately. Each will have a total weight of 100 points.**

CRITERIA **WEIGHT**

PART A - PRIMARY IMMUNODECIENCY DISEASE (PID) CONSORTIUM TOTAL: 100 POINTS

A. Technical Capabilities **55 points**

1. Scientific rationale, suitability, and feasibility of: **(20 points)**

(a) Scientific agenda, including approaches to solicit, peer-review, award and evaluate progress of pilot/small studies; and mentor and build collaborations.

(b) Detailed design of the proposed two to four research studies, which may or may not be approved by the Government to be conducted in the first year of the Contract, and two of which much be a clinical research project.

(c) Identified knowledge gaps, scientific opportunities and obstacles to progress relevant to primary immunodeficiency disease research.

2. Scientific rationale, suitability, and feasibility of: **(20 points)**

(a) Proposed plan to establish a Registry and transition data from the current Primary Immunodeficiency Disease Registry; plan to maintain the Registry; and plan to ensure maximal patient registration and follow-up and utilization of the Registry, including the approval process.

(b) Database development to include sophisticated search capability and web-based use and data entry. How security issues will be addressed.

(c) Proposed closeout and transition plan for the Registry and Consortium.

3. Effectiveness, suitability, and feasibility of the Management Plan: **(15 points)**

Proposed plan for management and coordination of the Consortium (and the Primary Immunodeficiency Disease Registry) including organizational structure, chain of command, operating procedures, timelines, decision-making processes, governance, and functions of committees and subcommittees that will provide successful management of the Consortium.

B. Personnel Qualifications **35 points**

1. Leadership and Management structure:

Proposed scientific, clinical, technical and administrative leadership qualifications of the Consortium Primary Investigator and Steering Committee members, including knowledge; experience; competence; education; success in designing, implementing, completing and publishing the results of research studies; and leadership competency of the proposed PI to manage successfully a project of this size and complexity. The following is a mandatory requirement that will become part of an advanced understanding in the contract: The PI must be a leading academic investigator in primary immunodeficiency disease research, a non-Federal employee, and must devote at least 10% effort to the contract.

2. Scientific, Clinical, Technical and Administrative Staff

Documented training, experience, competence and availability of the proposed other professional, technical, and administrative staff, documented ability to perform their roles in proposed studies, expertise in similar projects, and the time commitment of the other professional, technical and administrative staff.

3. Subcontractor(s) (if applicable)

Documented training, experience and availability of proposed subcontractor(s), their documented capability to perform the proposed work, expertise in similar projects, and the time commitment proposed.

4. Management of subcontractors (if applicable)

Quality of the scientific plan to identify the need to add, replace, or remove scientific and technical staff of proposed subcontractor(s), dependent on progress or changes in scientific direction.

C. Facilities and Resources **10 points**

Documented availability and adequacy of facilities, equipment and resources, including shared resources, necessary to carry out all phases of the proposed project.

PART B –OPTION- CELL REPOSITORY **TOTAL: 100 POINTS**

A. Technical Capabilities **45 points**

Scientific Rationale, Suitability and Feasibility of

(1) The proposed plan and approach to set priorities, collect specimens, establish cell lines and maintain a cell repository of primary immunodeficiency disease Registry patients and plan to provide Repository non-viable cells, as a source of DNA, for approved research studies. The demonstrated ability to establish cell lines.
(2) Computer management system, including security issues.
(3) Proposed closeout or transition plan for the Repository.

B. Personnel Qualifications **30 points**

Documented training, experience and availability of proposed Director or subcontractor(s) and other key personnel, their documented capability to perform the proposed work, expertise in similar projects, and the time commitment proposed.

C. Facilities and Resources **25 points**

Documented availability and adequacy of facilities, equipment and resources, including shared resources, necessary to carry out all phases of the proposed project.

ATTACHMENT A
Please return to:

For internal use only:

Patient Identifying # _____

Hyper IgM Registry Clinical Data Entry Form

Patient Identifiers

Date of Birth: ____/____/____ MM DD YY

Initials: ____/____/___ First Middle Last

Gender:
☐ Male ☐ Female

Twin:
☐ No
☐ Yes
➥ Type: ☐ Identical ☐ Fraternal
➥ Gender: ☐ Male ☐ Female

Race/Ethnic Group: (check **all** that apply.)
☐ Caucasian ☐ Native American
☐ Asian ☐ Hispanic
☐ Black ☐ Other

Clinical Presentation Leading to Diagnosis **(Check *all* that apply.)**

☐ **Increased Susceptibility to Infections (e.g., recurrent, unusual or severe)**
☐ **Positive Family History**
☐ **Neutropenia**
☐ **Lymphadenopathy**
☐ **PCP Pneumonia**
☐ **Other: _____**

Age at Onset of Symptoms *if applicable*:

_____ / _____
Years **Months**

Date of Diagnosis

_____ / _____
Years **Months**

Test Performed to Establish/Confirm Diagnosis (Check all that apply.)

Immunoglobulin Level at (closest to) Diagnosis:

		Low	Normal [for age]	High
IgG	_____	☐	☐	☐
IgA	_____	☐	☐	☐
IgM	_____	☐	☐	☐
	Level (IU/ml)			
IgE	_____	☐	☐	☐

Antibody Responses at (closest to) Diagnosis:

	Low	Normal	High
Diphtheria	☐	☐	☐
Tetanus	☐	☐	☐
Hib (PRP)	☐	☐	☐
Isoagluttin titers	☐	☐	☐
Pneumoccal Polysaccharide	☐	☐	☐
Others : _____	☐	☐	☐
_____	☐	☐	☐
_____	☐	☐	☐

Total Lymphocyte Count:
_____/mm^3

Lymphocyte Number Prior (closest) to Diagnosis:

CD2	CD3	CD4	CD8	CD19	CD20
____%	____%	____%	____%	____%	____%

Hyper Ig M

Lymphocyte Proliferation:

	Normal	Low	Absent	Not Done
PHA	☐	☐	☐	☐
CON A	☐	☐	☐	☐
Antigens _____	☐	☐	☐	☐
_____	☐	☐	☐	☐
_____	☐	☐	☐	☐
Alloantigens	☐	☐	☐	☐

Delayed Type Hypersensitivity Skin Tests:

	Present	Absent	Not Done
Tetanus	☐	☐	☐
Candida	☐	☐	☐
_____	☐	☐	☐
_____	☐	☐	☐
_____	☐	☐	☐
_____	☐	☐	☐

Form of Hyper IgM

☐ **X-linked Recessive**
☐ **Autosomal Recessive**
☐ Sporadic/Unknown: No mutation in CD40L
☐ Sporadic/Unknown: Not tested for mutation in CD40L

Method Used to Establish Genetic Basis

☐ Defect in CD40L Expression and/or CD40-IgG Binding
☐ Pedigree Analysis (see below)
☐ CD40L Mutation (please provide information below) **[Number nucleotides using EMBO J 11:4313, 1992]**

Nucleotides Affected (e.g., C361T): _____
Predicted Amino Acid Change (e.g., W140R): _____
Insertion/Deletion/Frameshift/Splice Site (please Explain) _____

_____

Should we consider mutation data confidential? _____
Publication - please give citation if mutation published _____

Family History (Check status for each family member. Indicate number in brackets if more than one.)

Family History Unknown ☐

	Tested Normal	Carrier	HIGM Alive	HIGM Dead		Not Tested
Mother	☐	☐	☐	☐	☐	
Father	☐	☐	☐	☐	☐	
Brothers (fill in #)	(____)	(____)	(____)	(__)		(___)
Sisters (fill in #)	(____)	(____)	(____)	(___)		(___)
Maternal uncles (fill in #)	(____)	(____)	(____)	(___)		(___)
Other (define & fill in #)	(____)	(____)	(____)	(___)		(___)
_____	(____)	(____)	(____)	(___)		(___)
_____	(____)	(____)	(____)	(___)		(___)
	(____)	(____)	(____)	(___)		(___)

Information on Other Affected Kindred Members (see above) (e.g.): a brother or uncle

Pedigree # _____
(for internal use only)

1 _____	_____	_____	2 _____	_____	_____	3 _____	_____	_____
Initials	**DOB**	**Gender**	**Initials**	**DOB**	**Gender**	**Initials**	**DOB**	**Gender**

Infection

Indicate episodes * as "Had Once" (1) or "Had>Once" (>1) with a check mark

	***Episodes P*rior to* Diagnosis**			***Episodes *After* Diagnosis**		
	1	>1	Organism (if known, list all)	1	>1	Organisms (if known, list all)
Pneumonia (e.g., PCP, CMV)						
Otitis						
Diarrhea (e.g., cryptosporidum)						
Sinusitis						
Sepsis						
Meningitis						
Encephalitis						
Arthritis (septic)						
Osteomyelitis						
Proctitis						
Abscess (specify organ)						
Pyoderma						
Peritonitis						
Hepatitis (specify organism/type)						
Sclerosing cholangitis						
Molluscum contagiosum						
Pavovirus B19						
Other: _____						
Other: _____						

Comments: _____ _____

Inflammatory/Autoimmune Disorders

Disorders	Present Prior to Diagnosis	Present After Diagnosis
Inflammatory Bowel Disease	☐	☐
Intestinal Nodular Hyperplasia	☐	☐
Arthritis (non-infectious)	☐	☐
Vasculitis	☐	☐
Oral Ulcers	☐	☐
Cirrhosis	☐	☐
Autoimmune Hemolytic Anemia	☐	☐
Other: _____	☐	☐
_____	☐	☐
Autoanitbodies:		
ANA positive	☐	☐
Anti neutrophil antibody	☐	☐
Anti platelet antibody	☐	☐
Coombs' positive (direct)	☐	☐
Other antibodies (specify):		
_____	☐	☐
_____		

Hematologic

	Present Prior to Diagnosis	Present After Diagnosis
Neutropenia (<1,000/mm^3)		
Chronic	☐	☐
Intermitten/Episodic	☐	☐
Anemia	☐	☐
Thrombocytopenia	☐	☐

Malignancy

Type (specify)	**Age at Diagnosis of Malignancy**
_____	
_____	

Other Clinical Features (supplemental information)

_____

_____

Treatment After Diagnosis

	Never	Intermitten	Constant
IM Gammaglobulin	☐	☐	☐
IVIG	☐	☐	☐
G-CSF	☐	☐	☐
Steroids	☐	☐	☐
Trimethoprim/Sulfa	☐	☐	☐
Other: _____	☐	☐	☐
_____	☐	☐	☐

Bone Marrow (stem cell) Transplant: ☐

Age at Transplant: _____ / _____
YRS MOS

Donor:
- Matched Sibling ☐
- MUD ☐
- Haploidentical ☐
- Family Member ☐
- Cord Blood ☐

Outcome:
- Alive and Well ☐
- Alive BUT:
  - Chronic GVH ☐
  - Growth Retardation ☐
  - Acute GVH
  - Liver Disease ☐
  - Died of BMT Related Problem ☐

Other Treatment: _____

_____

Current Status

Alive and Well: ☐

Alive BUT:
- Chronic Lung Disease ☐
- Cholangitis ☐
- Encephalitis ☐

Dead: ☐ Date of Death: _____ / _____ / _____
MM **DD** **YY**

Cause(s) of Death: _____

_____

Date of Last Contact with Patient (by phone or in person): _____ / _____ / _____
MM **DD** **YY**

Other Physicians Following Patient (name, address and phone of each)

_____

Please correct any errors in the information below:

Sample Only, MD #1234
University Hospital
2222 First Street
Town, MD 12345
Telephone: 410-222-1111

ATTACHMENT B
Please correct any errors on the label:

Sample Only, MD #1234
University Hospital
Pediatrics
2222 First Street
Town, MD 12345
Telephone: 410-222-1111

For internal use only:

Patient ID# SC _____

Severe Combined Immunodeficiency Disease Registry
Clinical Data Entry Form

Patient Identifiers

Initials: ____/____/___ (First Middle Last)

Date of Birth: ____/____/____ (MM DD YY)

Gender: ☐ Male ☐ Female

Twin: ☐ Yes ☐ No
If twin, please describe: _____

Race/Ethnic Group(s): (check *all* that apply.)
☐ Caucasian ☐ African American ☐ Asian ☐ Native American
If patient is *also* Hispanic, please check here: ☐

Clinical Presentation Leading to Diagnosis
Age at Onset of Symptoms *if applicable*:

_____/___ ___
Years Months

If Positive Family History contributed to Diagnosis, *please check here:* ☐

Problems Leading to or Prompting Diagnosis: (Check *all* that apply.)

☐ **PCP Pneumonia**
☐ **Vaccine-related Infection**
☐ **Enteroviral Infection**
☐ **Increased Susceptibility to Other Infections**
☐ **Chronic Dirrhea/Malabsorption/FTT**
☐ **Graft vs. Host Disease**
☐ **Other: _____**

SCID Diagnosed on: ____/____/____ **MM DD YY**

Or

Age at Diagnosis of SCID: _____/_____ **Years Months**

Or

Prenatal Diagnosis ☐

Tests Performed to Establish/Confirm Immune Defect (Check all that apply.)

Immunoglobulin Levels at (prior to) Diagnosis:

Level (mg/dl) [prior to IVIG]		Low	Normal [for age]	High
IgG	_____	☐	☐	☐
IgA	_____	☐	☐	☐
IgM	_____	☐	☐	☐
IgE		☐	☐	☐

Lymphocyte Numbers Prior (closest) to Diagnosis:

WBC _____ **%** **% Lymph** _____ **/mm³**
Absolute Lymph Count _____ **/mm³**

CD2	_____ %	**CD19**	%
CD3	_____ %	**CD20**	%
CD4	_____ %	**Sig**	%
CD8	%	**CD16/CD56**	%

Lymphocyte Proliferation:

	Absent	Low	Normal
Phytohemagglutinin (PHA)	☐	☐	☐
Concanavalin A (ConA)	☐	☐	☐
Pokeweed Mitogen (PWM)	☐	☐	☐
Antigens: _____	☐	☐	☐
_____	☐	☐	☐
Alloantigens (MLC)	☐	☐	☐

Delayed Type Hypersensitivity Skin Tests:

	Absent	Present
Tetanus	☐	☐
Candida	☐	☐
_____	☐	☐
_____	☐	☐
_____	☐	☐
	☐	☐

Form of SCID

X-Linked Recessive Deficiency:

☐ **Common Gamma-chain (gc)**

Autosomal Recessive Deficiency or Syndrome:

☐ **ADA** ☐ **Jak3** ☐ **Omenn** ☐ **Bare Lymphocyte** ☐ **RAG 1, 2** ☐ **ZAP 70** ☐ **Cartilage Hair Hypoplasia** ☐ **Other:** _____ ☐ **PNP** ☐ **IL-7Ra**

Sporadic/Inheritance:

☐ **Unknown**

☐ **Defect in Protein/Enzyme Expression**

☐ **Pedigree Analysis (corresponding to SCID Alive* and SCID Dead* in Family History table below.)**

☐ **Non-random X-chromosome Inactivation in Female Carrier (i.e., mother)**

☐ **Gene Mutation:** **Nucleotides Affected (e.g., 361C® T):** _____

[Number nucleotides using EMBO J 11:4313, 1992]

Predicted Amino Acid Change (e.g., W140R): _____

Insertion/Deletion/Frameshift/Splice Site (Explain.) _____

Publication or Mutation Database **Confidential?**

(Please cite & enclose copy *or* give ID#, database, web address &/or curator.)

Family History

☐ **Family History (If known, please provide information below.)**

☐ **Consanguinity (Explain.)** _____	**Tested Normal**	**Tested Carrier**	**Not Tested**	**SCID Alive ***	**SCID Dead ***
Mother	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐
Brothers (fill in #)	(____)	(____)	(____)	(__)	(___)
Sisters (fill in #)	(____)	(____)	(____)	(___)	(___)
Maternal uncles (fill in #)	(____)	(____)	(____)	(___)	(___)
Other (define & fill in #)	(____)	(____)	(____)	(___)	(___)
_____	(____)	(____)	(____)	(___)	(___)

***Information on Family Who are SCID Alive or SCID Dead as Listed Above (disregard Pt ID#)**

1. _____ _____ _____ _____
Relationship **Initials** **DOB** **Pt ID#**

2. _____ _____ _____ _____
Relationship **Initials** **DOB** **ID Pt #**

Treatment after Diagnosis

R_X	**Used Ever?**	**Transplant(s):**	**Other Therapy(s):**
IGIM/IGIV	☐	☐ **BMT**	_____
PEG – ADA	☐	☐ **Peripheral Stem Cell**	_____
Gene Therapy	☐	☐ **Core Blood Stem Cell**	_____

Status at Entry into Registry

☐ **Alive and Well** **Alive BUT:** ☐ **Chronic Lung Disease** ☐ **Chronic GVHD** ☐ **Encephalitis** ☐ **Other:**

☐ **Deceased** **Date of Death:** _____/_____/_____ **MM DD YY** **Cause(s) of Death:** _____ _____

Date of Last Contact with Patient (by phone or in person): _____/_____/_____ **MM DD YY**

Other Physicians Following Patient (please provide name, address and phone of each.)

_____

ATTACHMENT C

Leukocyte Adhesion Defect

Please correct any errors on the label:

Sample Only, MD #1234
University Hospital
Pediatrics
2222 First Street
Town, MD 12345
Telephone: 410-222-1111

For internal use only:
Patient ID# _____
Primary Contact _____

Leukocyte Adhesion Defect Registry
Clinical Data Entry Form
Patient Identifiers

Initials: ____/____/___ (First Middle Last)

Date of Birth: ____/____/____ (MM DD YY)

Gender:
☐ Male ☐ Female

Twin:
☐ No
☐ Yes
- ➥ Type: ☐ Identical ☐ Fraternal
- ➥ Gender: ☐ Male ☐ Female

Race/Ethnic Group(s): (check **all** that apply.)
☐ Caucasian ☐ Asian
☐ African American ☐ Native American
☐ Hispanic ☐ Non Hispanic

Clinical Presentation Leading to Diagnosis
Age at Onset of Symptoms

_____/_____
Years **Months**

Problems Leading to or Prompting Diagnosis: (Check *all* that apply.)
☐ **Increased Susceptibility to Infections (e.g. recurrent, unusual or severe)**
☐ **Positive Family History**
☐ **Leukocytosis**
☐ **Necrotic Ulceration of Skin**
☐ **Delayed Umbilical Separation**
☐ **Periodontitis/Gingivitis**
☐ **Other: _____**

LAD Diagnosed on:
____/____/____
MM DD YY

Test Performed to Establish/Confirm Diagnosis(Check all that apply.)
Flow Cytometry:

FACS	**Absent**	**Present**	**If Present, Meaan Channel Florescence (MCF)**	**Increase with Activation**
CD18	☐	☐	**Pt** _____ **NI** _____	☐
CD11a	☐	☐	Pt _____ NI _____	☐
CD11b	☐	☐	Pt _____ NI _____	☐
CD11c	☐	☐	Pt _____ NI _____	☐
CD15s	☐	☐	Pt _____ NI _____	☐

Adherence:
☐ **Nylon/Wool**
☐ **Glass/Plastic**
☐ **Cell to cell**

Blood Counts:
☐ **WBC elevated**
☐ **PMN elevated**

Genetic Information

☐ Pedigree Analysis (see Family History Below)

☐ CD18 or CD15s Mutation (please provide information below) **[Number nucleotides using EMBO J 11:4313, 1992]**

Nucleotides Affected (e.g., C361T): _____

Predicted Amino acid Change (e.g., W140R): _____

Insertion/Deletion/Frameshift/Splice Site (please explain) _____

Should we consider mutation data confidential? _____

Publication (please cite if published & enclose copy if possible) _____

Family History (check status **for each** family member. **Indicate numbers in brackets** if more than one affected.)

☐ Family History Unknown

	Tested Normal	Carrier	LAD Alive	LAD Dead	Not Tested
Mother	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐
Brothers (fill in #)	**(____)**	**(____)**	**(____)**	(__)	(___)
Sisters (fill in #)	**(____)**	**(____)**	**(____)**	(___)	(___)
Maternal uncles (fill in #)	**(____)**	**(____)**	**(____)**	(___)	(___)
Other (define & fill in #)	**(____)**	**(____)**	**(____)**	(___)	(___)
_____	**(____)**	**(____)**	**(____)**	(___)	(___)
_____	**(____)**	**(____)**	**(____)**	(___)	(___)
_____	**(____)**	**(____)**	**(____)**	(___)	(___)
	(____)	**(____)**	**(____)**	(___)	(___)

Information on Other Affected Kindred Members listed above (e.g., a sibling):

1. _____ _____ _____
   Initials **DOB** **Gender**
2. _____ _____ _____
   Initials **DOB** **Gender**
3. _____ _____ _____
   Initials **DOB** **Gender**
4. _____ _____ _____
   Initials **DOB** **Gender**

Kindred: _____
(internal use only)

Major Illnesses Related to LAD (Check **all** that apply.)

		Had Once	Had >Once	Organisms
☐	Sinusitis			
☐	Otitis			
☐	Pneumonia			
☐	Perianal Ulceration			
☐	Suppurative Adenitis			
☐	Osteomyelitis			
☐	Cellulitis			
☐	Sepsis			
☐	Lung Abscess			
☐	Colitis/Enteritis			
☐	Appendicitis with Perforation			
☐	Skin Ulcers			
☐	Delayed Wound Healing			
☐	Brain Abscess			
☐	Subcutaneous Abscess			
☐	Meningitis			
☐	Periodontal Disease			
☐	Oral (apthous) Ulcers			
☐	Other:			

☐ None of these

Other Diseases (Check **all** that apply.)

☐ Cancer ➲ Type: _____

☐ Arthritis ➲ Type: _____

☐ Other Autoimmune Disease ➲ Type: _____

☐ Atherosclerosis

☐ Hypertension

☐ Stroke

☐ Other: _____

☐ None of these

Treatment After Diagnosis

	Never	Intermitten	Constant
Trimethoprim/Sulfa (Bactrim/Septra)	☐	☐	☐
Dicloxacillin/Keflex	☐	☐	☐
Granulocyte Transfusions	☐	☐	☐
Steroids	☐	☐	☐
Periodontal Therapy	☐	☐	☐
Other Long Term/Prophylactic Therapy	☐	☐	☐
Other: _____	☐	☐	☐

☐ Bone Marrow (or Stem Cell) Transplant

Age at Transplant _____ / _____

Years Months

Outcome:

- ☐ Alive and Well
- Alive BUT:
  - ☐ Chronic GVH Disease
  - ☐ Acute GVH Disease
  - ☐ Growth Retardation
  - ☐ Liver Disease
  - ☐ Died of BMT Related Problem

Donor:

- ☐ Matched Sibling
- ☐ Matched Unrelated Donor
- ☐ Haploidentical
- ☐ Family Member
- ☐ Cord blood

Current Status

☐ Alive and Well ☐ Alive BUT:

_____

_____

☐ Dead Date of Death:

_____ / _____ / _____

MM **DD** **YY**

Cause(s) of Death: _____

_____

Date of Last Contact with Patient (by phone or in person): _____ / _____ / _____

MM **DD** **YY**

Other Physicians Following Patient (name address and phone of each)

_____

Sample Only, MD #1234
University Hospital
Pediatrics
2222 First Street
Town, MD 12345
Telephone: 410-222-1111

ATTACHMENT D
CGD

Physician # _____

CHRONIC GRANULOMATOUS DISEASE REGISTRY
CLINICAL DATA ENTRY FORM

PATIENT IDENTIFIERS

DATE OF BIRTH: _____ / _____ / _____ INITIALS: _____
MM DD YY

Gender: ☐ Male ☐ Female

Twin:

☐ NO ☐ Yes

Type: ☐ Identical ☐ Fraternal

Twins Gender ☐ Male ☐ Female

Racial Group: (Please check all that apply.)

☐ Caucasian ☐ Black
☐ Asian ☐ Native American

Ethnic Group: (Please check all that apply.)

☐ Hispanic ☐ Non-Hispanic

DIAGNOSTIC TESTS PERFORMED TO ESTABLISH/CONFIRM (Check all that apply.)

☐ Nitroblue tetrazolium test (NBT)
  ☐ Slide ☐ Quantitive
☐ Superoxide production
☐ Hydrogen peroxide production
☐ Oxygen consumption
☐ Bacterial killing
☐ Chemiluminescence
☐ Dichlorofluorescein (DCF)
☐ Other _____
☐ None of the above

Date CGD Diagnosis Established _____ / _____ / _____
MM DD YY

☐ X-linked

☐ Autosomal recessive (check Type If Known)

- ☐ Defect in p22-phox (22 kDa Cytochrome b Subunit)
- ☐ Defect in p47-phox (47 kDa Cytosolic component)
- ☐ Defect in p67-phox (67 kDa Cytosolic component)

☐ Not known

METHOD USED TO ESTABLISH GENETIC SUBTYPE (Check all that apply.)

☐ Cytochrome b spectral measurement Level _____ % of Normal

☐ Immunoblot analysis

Component _____ Level _____ % of Normal

(p22, p47, p67, gp91)

☐ Molecular genetic analysis of mutation

Mutation _____

☐ Pedigree analysis

☐ Genetic Subtype not known

FAMILY HISTORY (Check status for each family member. Indicate numbers in brackets if more than one affected.)

		AFFECTED			
	TESTED NORMAL	Carrier	CGD Alive	CGD Dead	NOT TESTED
Mother	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐
Brothers (fill in #)	☐ (__)	☐ (__)	☐ (__)	☐ (__)	☐ (__)
Sisters (fill in #)	☐ (__)	☐ (__)	☐ (__)	☐ (__)	☐ (__)
Maternal uncles (fill in #)	☐ (__)	☐ (__)	☐ (__)	☐ (__)	☐ (__)
Other Affected Family Members:					
		☐ (__)	☐ (__)	☐ (__)	
		☐ (__)	☐ (__)	☐ (__)	
		☐ (__)	☐ (__)	☐ (__)	
		☐ (__)	☐ (__)	☐ (__)	

☐ Family History Unknown

MAJOR ILLNESSES RELATED TO CGD (Check all that apply)

		Had 1 or Had >1	Organisms
☐	Pneumonia		
☐	Suppurative Adenitis		
☐	Osteomyelitis		
☐	Septic Arthritis		
☐	Sepsis		
☐	Lung Abscess		
☐	Liver Abscess		
☐	Brain Abscess		
☐	Subcutaneous Abscess		
☐	Meningitis		
☐	Gastric Outlet Obstructions		
☐	Urinary Outflow Obstructions		
☐	Colitis/Enteritis		
☐	Other: _____		
	_____		
☐	None of these		

☐ Cancer → Type: _____

☐ Arthritis

☐ Discoid Lubis Erythematosus → ☐ **Mother has DLE**

☐ Systemic Lupus Erythematosus → ☐ **Mother has SLE**

☐ Other autoimmune diseases → Type: _____

☐ Atherosclerosis

☐ Hypertension

☐ Stroke

☐ Other: _____

_____

☐ **None of these**

☐ X-linked

☐ Autosomal recessive (check Type If Known)

- ☐ Defect in p22-phox (22 kDa Cytochrome b Subunit)
- ☐ Defect in p47-phox (47 kDa Cytosolic comp onent)
- ☐ Defect in p67-phox (67 kDa Cytosolic component)

☐ Not known

METHOD USED TO ESTABLISH GENETIC SUBTYPE (Check all that apply.)

☐ Cytochrome b spectral measurement Level _____ % of Normal

☐ Immunoblot analysis

Component _____ Level _____ % of Normal

(p22, p47, p67, gp91)

☐ Molecular genetic analysis of mutation

Mutation _____

☐ Pedigree analysis

☐ Genetic Subtype not known

FAMILY HISTORY (Check status for each family member. Indicate numbers in brackets if more than one affected.)

		AFFECTED							
	TESTED NORMAL	Carrier		CGD Alive		CGD Dead		NOT TESTED	
Mother	☐	☐		☐		☐		☐	
Father	☐	☐		☐		☐		☐	
Brothers (fill in #)	☐ (__)	☐	(__)	☐	(__)	☐	(__)	☐	(__)
Sisters (fill in #)	☐ (__)	☐	(__)	☐	(__)	☐	(__)	☐	(__)
Maternal uncles (fill in #)	☐ (__)	☐	(__)	☐	(__)	☐	(__)	☐	(__)
Other Affected Family Members:									
		☐	(__)	☐	(__)	☐	(__)		
		☐	(__)	☐	(__)	☐	(__)		
		☐	(__)	☐	(__)	☐	(__)		
		☐	(__)	☐	(__)	☐	(__)		

☐ Family History Unknown

ATTACHMENT E

X Linked Agammaglobuline

Please correct any errors on the label: Sample Only, MD #1234
For internal use only:

➥ University Hospital
Pediatrics

Patient ID# **XL**_____

2222 First Street
Town, MD 12345
Telephone: 410-222-1111

X-Linked Agammaglobulinemia Registry
Clinical Data Entry Form

Patient Identifiers

Initials: _____ / _____ / _____ (First / Middle / Last)

Date of Birth: _____ / _____ / _____ (MM / DD / YY)

Gender:
☐ Male ☐ Female

Racial/Ethnic Group: (Check **all** that supply.)
☐ Caucasian ☐ Asian
☐ African American ☐ Native American
☐ Hispanic ☐ Non Hispanic

Twin:
➥ Type: ☐ Identical ☐ Fraternal
➥ Gender ☐ Male ☐ Female

Clinical Presentation Leading to Diagnosis

Age at Onset of Symptoms:
_____ / _____
Years **Months**

Problems Leading to or Prompting Diagnosis: (Check all that apply **&** enter on page 3 in detail.)
☐ Increased Susceptibility to Infections
☐ Positive Family History
☐ Vaccine-related Infection
☐ Enteroviral Infection
☐ Chronic Diarrhea/Malabsorption
☐ Arthritis
☐ Neutropenia
☐ Other: _____

XLA **Diagnosed** on: _____ / _____ / _____ (**MM** / **DD** / **YY**)

OR

Age at **Diagnosis** of XLA: _____ / _____ (**Years** / **Months**)

Tests Performed to Establish/Confirm Diagnosis (Check all that apply.)

Immunoglobulin Levels at (prior to) Diagnosis:

Level (mg/dl) [before IVIG]	Low	Normal [for age]	High
IgG _____	☐	☐	☐
IgA _____	☐	☐	☐
IgM _____	☐	☐	☐
IgG1 _____	☐	☐	☐
IgG2 _____	☐	☐	☐
IgG3 _____	☐	☐	☐
IgG4 _____	☐	☐	☐

Antibody Responses at (prior to) Diagnosis:

	Low	Normal	High
Diphtheria	☐	☐	☐
Tetanus	☐	☐	☐
H. influenzae B	☐	☐	☐
Isoagglutinin titers	☐	☐	☐
Pneumoccal polysaccharide	☐	☐	☐
Other: _____	☐	☐	☐
_____	☐	☐	☐
_____	☐	☐	☐

Lymphocyte Numbers Prior (closest) to Diagnosis:

Absolute Lymph Count	CD2	CD3	CD4	CD8	CD19	CD20	SIg^+
_____/mm3	_____ %	_____ %	_____ %	_____ %	_____ %	_____ %	_____ %

Method Used to Establish Genetic Basis (Check **all** that apply.)

☐ Less than 2% B Cells and Hypogammaglobulinemia (**if B cells** were **low or absent,** please **record on page 2** also.)

☐ Pedigree Analysis (see Family History below)

☐ BTK Expression Mutation (Please provide information belo w.) **[Number nucleotides using Nature 361:226, 1993]**

Nucleotides Affected (e.g., A229C): _____

Predicted Amino Acid Change (e.g., T33P): _____

Insertion/Deletion/Frameshift/Splice Site (Please explain.) _____

_____

Should we consider mutation data confidential? ☐ Yes ☐ No

Publication reporting genetic data (Please cite if published & enclose copy.) _____

_____

_____

Other publication(s) this patient appears in (Please cite…) _____

_____

_____

☐ Defect in BTK Expression

☐ Western ☐ Northern

☐ Non Random X-chromosome Inactivation in Female Carrier (i.e., Mother)

Family History

☐ Family History Unknown (if known, please provide information below.)

	Teste d Normal	**Tested Carrier**	**Not Tested**	**XLA Alive ***	**XLA Dead ***
Mother	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐
Brothers (fill in #)	(___)	( )	( )	( )	( )
Sisters (fill in #)	( )	( )	( )	( )	( )
Maternal uncles (fill in #)	( )	( )	( )	( )	( )
Other: (define & fill in #)	( )	( )	( )	( )	( )
_____	( )	( )	( )	( )	( )

* Information on Family Members with XLA that are **Listed Above** (Pt ID# will be added internally.):

1. _____ **Relationship** _____ **Initials** _____ **DOB** _____ **Pt ID#**

2. _____ **Relationships** _____ **Initials** _____ **DOB** _____ **Pt ID#**

3. _____ **Relationship** _____ **Initials** _____ **DOB** _____ **Pt ID#**

4. _____ **Relationships** _____ **Initials** _____ **DOB** _____ **Pt ID#**

5. _____ **Relationship** _____ **Initials** _____ **DOB** _____ **Pt ID#**

6. _____ **Relationships** _____ **Initials** _____ **DOB** _____ **Pt ID#**

Pedigree _____
(for internal use only)

A**TTACHMENT F**

Di George Anomaly

Sample Only, MD #1234
University Hospital
Pediatrics
2222 First Street
Town, MD 12345

For internal use only:
Patient ID# DG _____

Please correct any errors on the label:

DiGeorge Anomaly (DGA) Registry

Clinical Data Entry Form

Patient Identifiers

Initials: ____/____/___ First Middle Last

Date of Birth: ____/____/____ MM DD YY

Gender:
☐ Male
☐ Female

Twin:
☐ Yes
☐ No
If twin, please describe: _____

Race/Ethnic Group(s): (check *all* that apply.)
☐ Caucasian ☐ Asian
☐ African American ☐ Native American
If patient is *also* Hispanic, please check here ☐

Clinical Presentation Leading to Diagnosis

Age at Onset of Symptoms *if applicable*:

_____/_____ Or _____

Problems Leading to or Prompting Diagnosis: (Check *all* that apply.)

☐ **Characteristic Facies**
☐ **Cardiac Anomalies**
☐ **Hypocalcemia &/or Seizures**
☐ **Graft vs. Host Disease**
☐ **Increased Susceptibility to Infections**
☐ **Other: _____**

DGA Diagnosed on: ____/____/____ **MM DD YY** **Or** **Age at Diagnosis of DGA:** _____/_____ **Years Months** **Or** **Prenatal Diagnosis** ☐

Test Performed to Establish/Confirm Immune Defect (Check all that apply.)

Immunoglobulin Levels at (prior to) Diagnosis:

IgG _____	☐	☐	☐	
IgA _____	☐	☐	☐	
IgM _____	☐	☐	☐	
IgE _____	☐	☐	☐	

Lymphocyte Numbers Prior (closest) to Diagnosis:

CD2 _____ %	**CD19** %		
CD3 _____ %	**CD20** %		
CD4 _____ %	**SIg** %		
CD8 _____ %	**CD16/CD 56** %		

Lymphocyte Proliferation:

	Absent	Low	Normal
Phytohemagglutinin (PHA)	☐	☐	☐
Concanavalin A (ConA)	☐	☐	☐
Pokeweed Mitogen (PWM)	☐	☐	☐
Antigens: _____	☐	☐	☐
Alloantigens (MLC)	☐	☐	☐

Delayed Type Hypersensitivity Skin Tests:

	Absent	Present
Tetanus	☐	☐
Camdoda	☐	☐
_____	☐	☐
_____	☐	☐
_____	☐	☐

Additional Test Results &/or method(s) Used to Establish Diagnosis (Check all that apply.)

☐ **Chromosomal/FISH Analysis**
☐ **Mutation in Gene**
☐ **Pedigree Analysis (corresponding to *DGA Alive** and *DGA Dead** in Family History table below)**
☐ **Characteristic Clinical Features**
☐ **Other:** _____

Family History

☐ **Family History (If known, please provide information below.)**

***If known,* please provide information here:**

	Tested Normal	Tested Carrier	Not Tested	DGA Alive*	DGA Dead*
Mother	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐
Brothers (fill in #)	(____)	(____)	(____)	(__)	(___)
Sisters (fill in #)	(____)	(____)	(____)	(___)	(___)
Maternal uncles (fill in #)	(____)	(____)	(____)	(___)	(___)

Infections

Indicate episodes* as "Had Once" (1) or "Had More Than Once" (>1) with a check mark.	* Episodes *Prior* To Diagnosis: 1	>1	Organism (if known, list all)	* Episodes *After* Diagnosis: 1	>1	Organism (if known, list all)
Pneumonia						
Otitis						
Conjunctivitis						
Sinusitis						
Sepsis						
Meningitis						
Encephalitis						
Arthritis						
Osteomyelitis						
Diarrhea (e.g., Giardia)						
Proctitis						
Cellulitis						
Abscess (specific organ)						
Pyoderma						
Peritonitis						
Enterovirus						
Hepatitis (specific organism/type)			☐ A ☐ B ☐ C ☐ Other: _____			☐ A ☐ B ☐ C ☐ Other: _____
Complication of live virus immunization			☐ Polio ☐ MMR* ☐ Varicella Please indicate which one.			☐ Polio ☐ MMR* ☐ Varicella Please indicate which one.
Other: _____						
Other: _____						

Comments: _____

Other Diseases

☐ Anemia ☐ Neutropenia ☐ Lymphopenia ☐ Unexplained CNS Deterioration

☐ ITP ☐ Cystitis/Prostatitis/Epidedymitis

☐ Henoch-Schönlein Purpura

☐ Vasculitis

☐ Inflammatory Bowel Disease/Malabsorption

☐ Hepatitis

☐ Dermatomyositis

☐ Arthritis:

- ☐ JRA
- ☐ RA
- ☐ Unknown Etiology

☐ Other: _____

Malignancy

☐ Malignancy Type: _____ Age of Onset: _____ / _____
Years **Months**

Treatment After Diagnosis

	Intermittent	Constant
Plasma Therapy	☐	☐
IMIG	☐	☐
IVIG	☐	☐
Steroids	☐	☐
Prophylactic Antibiotics	☐	☐
Other: _____	☐	☐

☐ Splenectomy Age: _____ / _____ Indication: _____
Years **Months**

☐ Organ Transplant Age: _____ / _____ Location/Organ: _____
Years **Months**

Status at Entry into Registry

Alive and Well ☐

Alive BUT:

- ☐ Chronic Lung Disease
- ☐ Encephalitis
- ☐ Other: _____

Deceased ☐ Date of Death: _____ / _____ / _____
MM **DD** **YY**

Cause(s) of Death: _____

Date of Last Contact with Patient (by phone or in person): _____ / _____ / _____
MM **DD** **YY**

Other Physicians Following Patient (Please provide **name, address and phone** of each.)

_____

ATTACHMENT G

Wiskott Aldrich Syndrome

Please correct any errors on the label:

➥ Sample Only, MD #1234
University Hospital
Pediatrics
2222 First Street
Town, MD 12345
Telephone: 410-222-1111

For internal use only:

Patient ID# **WA**_____

Wiskott-Aldrich Syndrome Registry
Clinical Data Entry Form

Patient Identifiers

Initials: _____ / _____ / _____
First Middle Last

Date of Birth: _____ / _____ / _____
MM DD YY

Gender:
☐ Male ☐ Female

Twin:
☐ No
☐ Yes
➥ TYPE: ☐ Identical ☐ Fraternal
➥ GENDER ☐ Male ☐ Female

Racial/Ethnic Group: (Check **all** that supply.)
☐ Caucasian ☐ Asian
☐ African American ☐ Native American
☐ Hispanic ☐ Non Hispanic

Clinical Presentation Leading to Diagnosis

Age of Onset of Symptoms:
_____ / _____
Years **Months**

Problems Leading to or Prompting Diagnosis: (Check all that apply.)
☐ Increased Susceptibility to Otitis Media
☐ Increased Susceptibility to Other Infections (e.g., recurrent, unusual or severe)
☐ Bleeding, Petechiae
☐ Thrombocytopenia
☐ Eczema
☐ Positive Family History
☐ Other: _____

WAS Diagnosed on:
_____ / _____ / _____
MM DD YY

Tests Performed to Establish/Confirm Diagnosis (Check **all** that apply.)

Typical Platelet Count at Diagnosis:
☐ <10,000
☐ 10 - 20,000
☐ 20 - 50,000
☐ 50 - 100,000
☐ 100 - 150,000

Platelet Volume (Pre-splenectomy):
_____ femtoliters

Platelet Diameter (Pre-splenectomy):
_____ microns

Immunoglobulin Levels at (closest to) Diagnosis:

Level (mg/dl) [before IVIG]	Low	Normal [for age]	High
IgG _____	☐	☐	☐
IgA _____	☐	☐	☐
IgM _____	☐	☐	☐
Level (IU/ml)	☐	☐	☐
IgE _____	☐	☐	☐

Total Lymphocyte Count:
_____ /mm^3

Antibody Responses at (closest to) Diagnosis:

	Low	Normal [before IVIG]	High
Diphtheria	☐	☐	☐
Tetanus	☐	☐	☐
Hib	☐	☐	☐
Isoaglutinin Titers	☐	☐	☐
Pneumoccal Polysaccharide	☐	☐	☐
ÔX174	☐	☐	☐
Other: _____	☐	☐	☐
_____	☐	☐	☐

Lymphocyte Subsets Prior (closest) to Diagnosis:

CD2	CD3	CD4	CD8	CD16	CD19	CD20
_____ %	_____ %	_____ %	_____ %	_____ %	_____ %	_____ %

Lymphocyte Proliferation:

	Absent	Low	Normal
PHA	☐	☐	☐
CON A	☐	☐	☐
Antigens _____	☐	☐	☐
_____	☐	☐	☐
_____	☐	☐	☐
Alloantigens	☐	☐	☐

Delayed Type Hypersensitivity Skin Tests:

	Absent	Present
Tetanus	☐	☐
Candida	☐	☐
_____	☐	☐
_____	☐	☐
_____	☐	☐
_____	☐	☐

Form of WAS

☐ X-linked Recessive ☐ Sporadic

Genetic Information

☐ Pedigree Analysis (See Family History on next page.)

☐ WAS (Protein) Defect

☐ WAS (Gene) Mutation (Please provide information below.) **[Number nucleotides using EMBO J 11:4313, 1992]**

Nucleotide Affected (e.g., C361T) _____
Predicted Amino Acid Change (e.g., W140R) _____
Insertion/Deletion/Frameshift/Splice Site (Please explain.) _____
_____
Should we consider mutation data confidential? _____
Publication (Please cite if published & enclose copy if possible.) _____
_____

☐ Skewed X-chromosome Inactivation in Mother or Other Female Carrier

Cell(s)/Tissue(s) Tested _____

Family History (Check **status for each** family member. Indicate **numbers in parentheses** if more than one affected.)

☐ Family History Unknown

	Tested Normal	Carrier	Not Tested	WAS Alive	WAS
Dead					
Mother	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐
Brothers (fill in #)	(____)	(____)	(____)	(____)	(____)
Sisters (fill in #)	(____)	(____)	(____)	(____)	(____)
Maternal uncles (fill in #)	(____)	(____)	(____)	(____)	(____)
Other: _____ fill in #)	(____)	(____)	(____)	(____)	(____)
_____	(____)	(____)	(____)	(____)	(____)
_____	(____)	(____)	(____)	(____)	(____)

Information on Other Affected Kindred Members listed above: (e.g., a sibling, cousin &/or maternal uncle.)

1. _____ _____ _____ 2. _____ _____ _____ _____
Initials DOB Gender Initials DOB Gender
Family ID#

(for internal use)

3. _____ _____ _____ 4. _____ _____ _____
Initials DOB Gender Initials DOB Gender

Major Infections Related to WAS (Check **all** that apply.)

	Had Once	Had > Once	Organism(s)
☐ Otitis	_____	_____	_____
☐ Pneumonia	_____	_____	_____
☐ Infectious Diarrhea	_____	_____	_____
☐ Sinusitis	_____	_____	_____
☐ Sepsis	_____	_____	_____
☐ Meningitis	_____	_____	_____
☐ Varicella	_____	_____	_____
☐ Epstein-Barr Virus	_____	_____	_____
☐ Cytomegalovirus (CMV)	_____	_____	_____
☐ Herpes Simplex Virus I or II	_____	_____	_____
☐ Parvovirus B19	_____	_____	_____
☐ Polyomavirus	_____	_____	_____
☐ Molluscum Contagiosum	_____	_____	_____
☐ Pneumocystic Carinii	_____	_____	_____
☐ Osteomyelitis	_____	_____	_____
☐ Cellulitis	_____	_____	_____
☐ Suppurative Adenitis	_____	_____	_____
☐ Septic Arthritis	_____	_____	_____
Abscess:			
☐ Lung	_____	_____	_____
☐ Brain	_____	_____	_____
☐ Subcutuaneous	_____	_____	_____
Complication of Immunization:			
☐ Polio	_____	_____	_____
☐ Measles	_____	_____	_____
☐ Varicella	_____	_____	_____
☐ Other: _____	_____	_____	_____
☐ Other: _____	_____	_____	_____

Major Bleeding Episodes

- ☐ Upper GI Hemorrhage
- ☐ Lower GI Hemorrhage/Rectal Bleeding
- ☐ Intracranial
- ☐ Hemarthrosis
- ☐ Epistaxis
- ☐ Oral
- ☐ Hematuria

Autoimmune/Inflammatory Diseases

- ☐ Autoimmune Hemolytic Anemia
- ☐ Idiopathic Thrombocytopenia Purpura
- ☐ Schönlein-Henoch Purpura
- Lupus Erythmatosus:
  - ☐ Systemic
  - ☐ Discoid
- ☐ Neutropenia
- ☐ Vasculitis
- Arthritis:
  - ☐ Transient
  - ☐ Chronic
- ☐ Inflammatory Bowel Disease
- ☐ Dermatomyositis
- ☐ Other: _____

Other Diseases (Check **all** that apply.)

- ☐ Malignancy — Type: _____ Age of Onset: _____ / _____ **Years** **Months**
- ☐ Atherosclerosis
- ☐ Hypertension
- ☐ Stroke
- ☐ Other: _____

Treatment After Diagnosis

	Intermittent	Constant
IVIG	☐	☐
Steroids	☐	☐
Prophylactic Antibiotics	☐	☐
Other: _____	☐	☐

- ☐ Splenectomy

Age at Splenectomy: _____ / _____ **Years** **Months**

- ☐ Bone Marrow Transplant
- ☐ Stem Cell Transplant
- ☐ Cord Blood Transplant

Age at Transplant: _____ / _____ **Years** **Months**

Outcome:

- ☐ Alive and Well
- Alive BUT:
  - ☐ Chronic GVH Disease
  - ☐ Acute GVH Disease
  - ☐ Growth Retardation
  - ☐ Liver Disease
  - ☐ Only Partial Reconstitution
- ☐ Died of Transplant Related Problem

Donor;

- ☐ Matched Sibling
- ☐ Matched Unrelated Donor
- ☐ Haploidentical
- ☐ Family Member

Current Status

☐ Alive and Well

☐ Alive BUT:

_____

_____

_____

☐ Dead

Date of Death:

_____ / _____ / _____

MM **DD** **YY**

Cause(s) of Death: _____

_____

Date of Last Contact with Patient (by phone or in person): _____ / _____ / _____

MM **DD** **YY**

Other Physicians Following Patient (Please provide **name, address and phone** of each.)

_____

_____

ATTACHMENT H

Common Variable Immune Deficiency

Please correct any errors on the label: Sample Only, MD #1234
For internal use only:

➥ University Hospital
Pediatrics

Patient ID# **CV**_____

2222 First Street
Town, MD 12345
Telephone: 410-222-1111

Common Variable Immune Deficiency Registry
Clinical Data Entry Form

Patient Identifiers

Initials: _____ / _____ / _____ (First / Middle / Last)

Date of Birth: _____ / _____ / _____ (MM / DD / YY)

Gender:
☐ Male ☐ Female

Twin:
☐ No
☐ Yes
➥ TYPE: ☐ Identical ☐ Fraternal
➥ GENDER ☐ Male ☐ Female

Racial/Ethnic Group: (Check **all** that supply.)
☐ Caucasian ☐ Asian
☐ African American ☐ Native American
☐ Hispanic ☐ Non Hispanic

Clinical Presentation Leading to Diagnosis

Age at Onset of Symptoms:
_____ / _____
Years **Months**

Problems Leading to or Prompting Diagnosis: (Check **all** that apply.)
☐ Increased Susceptibility to Infections
☐ Autoimmune/Rheumatic Disease(s)
☐ Chronic Diarrhea/Malabsorption
☐ Lymphadenopathy
☐ Positive Family History
☐ Other: _____

CVID Diagnosed on: _____ / _____ / _____ (**MM** / **DD** / **YY**)

OR

Age at Diagnosis of CVID: _____ / _____ (**Years** / **Months**)

Tests Performed to Establish/Confirm Diagnosis (Check all that apply.)

Immunoglobulin Levels at (prior to) Diagnosis:

Level (mg/dl) [before IVIG]	Low	Normal [for age]	High
IgG _____	☐	☐	☐
IgA _____	☐	☐	☐
IgM _____	☐	☐	☐
IgG1 _____	☐	☐	☐
IgG2 _____	☐	☐	☐
IgG3 _____	☐	☐	☐
IgG4 _____	☐	☐	☐

Antibody Responses at (prior to) Diagnosis:

	Low	Normal	High
Diphtheria	☐	☐	☐
Tetanus	☐	☐	☐
Hib	☐	☐	☐
Isoaglutinin Titers	☐	☐	☐
Pneumoccal Polysaccharide	☐	☐	☐
Other: _____	☐	☐	☐
_____	☐	☐	☐
_____	☐	☐	☐

Lymphocyte Numbers Prior (closest) to Diagnosis:

Absolute Lymphocyte Count	CD2	CD3	CD4	CD8	CD19	CD20
_____/mm3	_____ %	_____ %	_____ %	_____ %	_____ %	_____ %

Lymphocyte Proliferation:

	Absent	Low	Normal
PHA	☐	☐	☐
CON A	☐	☐	☐
Anti - CD3	☐	☐	☐
Antigens: _____	☐	☐	☐
_____	☐	☐	☐
Other: _____	☐	☐	☐

Delayed Type Hypersensitivity Skin Tests:

	Absent	Present
Tetanus	☐	☐
Candida	☐	☐
_____	☐	☐
_____	☐	☐
_____	☐	☐
_____	☐	☐

Family History

☐ Family History Unknown

☐ Family History Positive (If positive, **please** fill in below, **use M** for Maternal **& P** for Paternal, **when indicated.)**

Affected Family Member. Please indicate Mother, Father, Son, Daughter, Brother, Sister, MGM, PGM, etc.	CVID *	IgA Selective Deficiency	Leukemia/ Lymphoma	Other Malignancy	Lupus Erythmatosus	Thyroiditis	Idiopathic Thrombocytopenia Purpura (ITP)	Sarcoidosis (Granulomatous Disease)	Autoimmune Hemolytic Anemia (AIHA)	Inflammatory Bowel Disease (IBD)

* Information on Family Members with CVID that are **Listed Above** (Pt ID# will be added internally):

1. _____ _____ _____ _____ 2. _____ _____ _____ _____ 3. _____ _____ _____ _____
   Relation Initials DOB Pt ID# Relation Initials DOB Pt ID Relation Initials DOB Pt ID#

4. _____ _____ _____ _____ 5. _____ _____ _____ _____ 6. _____ _____ _____ _____
   Relation Initials DOB Pt ID# Relation Initials DOB Pt ID Relation Initials DOB Pt ID#

Pedigree _____

(for internal use only)

Major Infections Related to CVID (Check all that apply.)

	Had Once	Had > Once	Organism(s) or Location(s) **(if known)**
☐ Sinusitis			
☐ Otitis			
☐ Bronchitis			
☐ Pneumonia (**not PCP)**			
☐ Pneumocystic carinii pneumo nia (PCP)			
☐ Infectious diarrhea			
☐ Sepsis			
☐ Meningitis/Encephalitis			
☐ Hepatitis			☐ A ☐ B ☐ C ☐
Other:			
☐ Cellulitis			
☐ Osteomyelitis			
☐ Suppurative adenitis			
☐ Septic arthritis			
☐ Abscess in lung			
☐ Abscess in brain			
☐ Abscess subcutaneous			
☐ Tuberculosis			
☐ Atypical mycobacterium			
☐ Histoplasmosis			
☐ Epstein-Barr virus			
☐ Cytomegalovirus (CMV)			
☐ Herpes simplex virus I or II			
☐ Herpes zoster			
☐ Parvovirus B19			
☐ Warts/Papilloma virus			
☐ Molluscum contagiosum			
☐ Complication of live virus immunization			☐ Polio ☐
Measles ☐ Varicella			
☐ Other: _____			
☐ Other: _____			